

REMARKS

1. Status of claims

After entry of the above amendment, claims 82-102 and 125 are pending and under consideration. Claims 1-81 and 103-124 have previously been canceled.

2. Support for amendment

The amendment finds support in the specification at p. 12, lines 4-18. No new matter has been added by this amendment.

3. Claim rejections under 35 U.S.C. § 103(a)

The Examiner rejected claims 82-88 and 91-102 as being unpatentable over Mechanic, US 5,854,397 ("Mechanic") in view of Gan, *et al.*, US 5,964,807 ("Gan"). In light of the above amendment, Applicants respectfully traverse this rejection.

By the above amendment, claim 82 and all claims dependent thereon recite obtaining nucleus pulposus tissue harvested from a donor; and cross linking at least a portion of the harvested nucleus pulposus tissue.

The Examiner alleges Mechanic teaches a process for crosslinking proteinaceous material and Gan teaches a hybrid material comprising intervertebral disc cells and a biodegradable support substrate, wherein the intervertebral disc cells are nucleus pulposus cells which may be obtained from the patient or from donor tissue. The Examiner further alleges the person of ordinary skill in the art would then find it obvious to use the hybrid material of Gan in the process of Mechanic, which would then allegedly produce the method recited by the present claims.

Mechanic fails generally to teach a method of manufacturing an intervertebral disc implant and, as noted by the Examiner, specifically “does not teach nucleus pulposus tissue,” especially nucleus pulposus tissue comprising native collagen and native proteoglycan aggregates. Gan teaches the use of donor nucleus pulposus *cells*, but not tissue harvested from a donor *per se*. Although Gan notes “tissue may be extracted from the nucleus pulposus of lumbar discs, sacral discs and cervical discs,” the collagen and other components of that tissue subsequently are discarded to obtain isolated nucleus pulposus cells. These isolated cells are then combined with materials intended to substitute for the discarded nucleus pulposus tissue collagen and other components from which they were isolated. Throughout the specification, Gan repeatedly emphasizes the mechanical and chemical destruction of the nucleus pulposus tissue to liberate cells for use in creating a hybrid matrix containing bioactive glass, polymer foam, and polymer foam coated with a sol gel bioactive material (col. 6, lines 30-32). Gan also makes no mention of crosslinking nucleus pulposus material. As such, any combination of Gan and Mechanic by a person of skill in the art would lead him or her to contemplate crosslinking the bioactive glass, polymer foam, or polymer foam coated with a sol gel bioactive material of Gan according to the methods of Mechanic. The combination would not lead the skilled artisan to the presently claimed invention.

Therefore, Applicants submit claims 82-88 and 91-102 are patentable over Mechanic in view of Gan and request this rejection be withdrawn.

Second, the Examiner rejected claims 89-90 as being unpatentable over Mechanic in view of Gan and further in view of Moore, *et al.*, US 6,350,732 (“Moore”). The Examiner alleges Moore teaches a method for extracting lipids from a collagenous tissue sample. Applicants respectfully traverse this rejection.

Mechanic and Gan have been discussed above with respect to independent claim 82 and claims dependent thereon. As a threshold matter, claims 89-90, which also depend on claim 82 are patentable for at least the reasons noted above. In addition, Moore, like Mechanic, fails to teach nucleus pulposus tissue harvested from a donor and does nothing to remedy the deficiencies of Gan regarding the use of nucleus pulposus tissue *per se*. As such, the teachings of Moore with those of Mechanic and Gan would not lead the person of ordinary skill in the art to the presently claimed invention.

Therefore, Applicants submit claims 89-90 are patentable over Mechanic in view of Gan and Moore and request this rejection be withdrawn.

4. *Conclusion*

Applicants submit all pending claims are in condition for allowance. The Examiner is invited to contact the undersigned patent agent at (713) 934-4065 with any questions, comments or suggestions relating to the referenced patent application.

Should any fees under 37 C.F.R. §§ 1.16 to 1.21 be required for any reason, the Director is authorized to deduct said fees from Williams, Morgan & Amerson, P.C. Deposit Account No. 50-0786/2103.013882RE.

Respectfully submitted,

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